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Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 02N-0276
Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir or Madam:

The National Coffee Association of USA (NCA) appreciates the opportunity to submit comments on the above referenced proposed rule, as published in the Federal Register (68 FR 5378, February 3, 2003).

NCA represents the US coffee industry, which generates $18 billion annually in sales and conducts $3 billion in trade with 30 countries from Asia, Africa and Latin America. In addition to the more than one thousand roasters and importers, the industry is comprised of some 10,000 coffee cafés employing persons in every state and region. Through retail, restaurant and coffee café sales the industry serves 177 million consumers annually. NCA membership, consisting, in part, of coffee growers, exporters, importers and roasters, will be impacted by the Bioterrorism Preparedness and Response Act and associated regulations.

The Food and Drug Administration (FDA) is to be commended for its efforts in developing regulations in an expedited time frame in order to comply with the requirements set forth in section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 801) and with the statutory deadline of December 12, 2003, as provided in the Public Health Security

and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). The National Coffee Association shares the FDA's concern with regard to protecting the nation's food supply and therefore submits the comments contained herein for the purpose of clarification in some cases, and to simplify the requirements set forth in the above referenced regulation, thereby facilitating the protection of the U.S. food supply, while at the same time fully meeting the statutory requirements of the Bioterrorism Act.

The heightened urgency of promulgating the above referenced regulations places extreme importance on developing a final rule that is not overly broad, thereby facilitating compliance and enforcement, and most importantly protecting the U.S. food supply by facilitating FDA's response to a threatened or actual terrorist attack. As proposed, the regulation is overly broad in scope and in some instances exceeds statutory authority. These additional arbitrary requirements overly complicate the registration process, and as a result of the added burden the regulation, as proposed, could hamper the FDA in acting quickly in responding to a threatened or actual terrorist attack on the U.S. food supply.

As a general note, the proposed regulation implies that it is the owner, operator, or agent in charge that must be registered. This is contrary to the Bioterrorism Act, which requires that the facility be registered. In fact, section 1.230 expressly states "the owner, operator, or agent in charge of a facility that manufactures/processes, holds or packs food for consumption in the United States must be registered no later than December 12, 2003" [emphasis supplied]. This section, taken in concert with sections 1.225 and 1.226, as well as with the information requested in the Draft Food Facility Registration Form (68 FR 5421, might be subject to considerable misinterpretation as time passes. As such, the NCA encourages the FDA to incorporate the necessary amendments to clarify that it is the facility that must be registered, not the owner, operator, or agent in charge.

Definitions (Section 1.227)

Section 1.227(c)(8) defines the term "packing." However, the terms "packaging" and "pack" are used in sections 1.226(a) and 1.230, respectively. Although arguably the terms pack and packing could be used interchangeably, the term "packaging" is materially different. Unless it is the intent of the FDA to indicate a material difference through the use of distinctive terms, it is recommended that the regulation be revised in a manner that provides for consistent use of language. Should the FDA's intent be to indicate a material difference, it is strongly suggested that the term "packaging" be defined in section 1.227.

Clarification is needed to avoid misinterpretation, especially considering the fact that the definition of food (§ 1.227(c)(4)) alludes to packaging material as being considered food for purposes of the regulation. Additional comments on the definition of food are provided below under the heading "Scope of Registration

Provisions."

Further, section 1.227(c)(12) defines a U.S. agent as "a person residing or maintaining a place of business in the Untied States..." [emphasis supplied]. NCA encourages FDA to further amend this section, thereby clarifying that the term "person" includes an individual, partnership, corporation, and association, as is consistent with section 201(e) of the Federal Food, Drug, and Cosmetic Act, wherein person is defined as such.

In addition, NCA notes that in section 1.227(c)(12) the FDA correctly limits the responsibility of an agent to acting "...as a communications link between FDA and the facility," therefore not charging the agent with additional obligations. For purposes of clarification, the NCA urges the FDA to provide additional language clearly defining the agent's exact role.

Scope of Registration Provisions

The scope of the proposed regulation is considerably broader than mandated or authorized by the Bioterrorism Act. In order to facilitate the protection of the U.S. food supply by facilitating FDA's response to a threatened or actual terrorist attack, the FDA is urged to limit the scope of the provisions in a manner that more closely conforms to the statutory language provided in the Bioterrorism Act.

Specifically, the regulation is open for misinterpretation regarding "a mobile facility traveling to multiple locations" as used in section 1.227(c)(2). Although NCA argues that the inclusion of transportation devices such as trucks, truck trailers, shipping containers and rail cars as facilities would be a misinterpretation of the regulation, the mere fact that some may interpret these devices as facilities argues for clarification. NCA notes that inclusion of transportation devices exceeds the statutory authority granted by the Bioterrorism Act, which expressly includes "manufacturing, processing, packing, or holding" facilities as within the scope of the Bioterrorism Act, but is silent with regard to transportation devices. Furthermore, to include transportation devices would unnecessarily over-burden the registration process and require a significant number of additional registered facilities in coffee producing nations, without providing a corresponding benefit regarding the facilitation of FDA's response to a threatened or actual terrorist attack. As such, NCA strongly encourages the FDA to provide clarification that transportation devices are not within the scope of the regulation.

Additionally, section 1.227(c)(4) defines food in a manner that exceeds congressional intent and is arbitrary and capricious. The Bioterrorism Act requires that facilities "...engaged in manufacturing, processing, packing, or holding food for consumption..." be registered [emphasis supplied]. Further, Congressman Shimkus clarified that "[s]ection 307 dealing with prior notice of imported food shipments should not be construed to apply to food packaging materials or other food contact substances if, at the time of importation, they are

not used in food." (Congressional Record at E916, May 22, 2002) However, the regulation incorrectly expands the scope to include facilities that do not process or hold food for consumption, such as facilities that may hold or manufacture indirect food additives, or food contact packaging. Again, the NCA urges FDA to correctly limit the scope of the regulation in a manner that conforms to the Bioterrorism Act, by clarifying the definition of "food" in a manner that only applies to food intended for consumption.

Required Information

Section 415(a)(2) of the Federal Food, Drug and Cosmetic Act, as amended by the Bioterrorism Act, expressly states that "an entity (referred to in this section as the 'registrant') shall submit a registration under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business..." [emphasis supplied]. Mandating the submission of additional information, as does section 1.232 of the proposed regulation, exceeds statutory authority. Further, providing much of the additional information will in many cases not be possible for foreign facilities associated with the coffee industry, because the information may not exist; this is especially the case with regard to fax numbers and email addresses and, at times, phone numbers. As such, the NCA strongly urges the FDA to amend section 1.232 as follows, and amend the Facility Registration Form (68 FR 5421) accordingly:

(a) The name~~,~~ and full address~~, phone number, fax number, and e-mail address~~ of the facility;

(b) A phone number for the facility;

~~(b) The name and address of the parent company, if the facility is a subsidiary of the parent company;~~

~~(c) Emergency contact information, including an individual's name, title, office phone, home phone, cell phone (if available), and e-mail address (if available);~~

~~(d)~~(c) All trade names the facility uses;

~~(e)~~(d) Product categories as identified in § 170.3 of this chapter;

~~(f)~~(e) For a foreign facility, the name, address, and phone number~~, fax number (if available), and email address (if available)~~ of its U.S. agent; and

~~(g)~~(f) A statement certifying that the information submitted is true and accurate, and that the person submitting the registration is authorized by the facility to register on its behalf. The statement requires the name and phone number of the person submitting the registration. ~~registering the facility. This statement also requires the phone number, e-mail address (if available), and fax number (if available) of the person submitting the~~

~~registration.~~

In submitting the above proposed amendments to section 1.232, the NCA does so without stipulating that statutory authority exists for the mandatory inclusion of a phone number. Further, NCA notes that as originally proposed in the regulation the phone number was required to be of a phone at or in the facility, i.e. "...phone number...of the facility." [emphasis supplied] The above proposed amendment requires a "phone number for the facility," thereby allowing for the submission of a phone number that might be used to contact personnel associated with the facility, but not of a phone necessarily at the facility. [emphasis supplied] This is especially important because facilities located in coffee producing nations may not have phone lines.

Security of Data

The NCA is extremely concerned about the security of data submitted to FDA in accordance with the above referenced regulation, especially considering the fact that the data may be accessible through the Internet. The FDA is strongly urged to employ measures that ensure the data is protected. Congressional intent is clear that the information collected pursuant to the Bioterrorism Act shall not be subject to disclosure under 5 U.S.C. 552. In fact, the Bioterrorism Act expressly exempts from disclosure "...any registration documents submitted pursuant to ...[the Bioterrorism Act]" and "[i]nformation derived from such list or registration documents..." (§415(a)(4) FFDCA) As such, the industry has an expectation that any and all information will be treated as privileged and confidential. Concern arises from the appearance that a registration number alone may provide access to a record. Access to a record with a registration number alone is troublesome, based in part, on the high probability that registration numbers which are required on the "Prior Notice Submission" form mandated in proposed Prior Notice of Imported Food regulations as published in 68 FR 5428, February 3, 2003, amending 21 CFR, Part 1, Subpart I, may become part of the commercial documentation between parties buying and selling coffee. Therefore, the FDA is urged to take any and all necessary actions/precautions to ensure the confidentiality of information submitted pursuant to the Bioterrorism Act.

Again, the National Coffee Association appreciates the opportunity to submit comments on the above referenced proposed regulation and looks forward to future opportunities to work with the Food and Drug Administration in the promulgation of regulations that protect the nation's food supply from terrorist attack.

Sincerely,

Robert F. Nelson